

WHAT IS CLAIMED IS:

1. A fluid reservoir for use with a drug delivery device, comprising:

- a sealed fluid chamber having a top surface and a bottom surface, and a cavity

therebetween, the cavity being at least partially defined by at least one seal, wherein the cavity serves to house a fluid therewithin;

- means for fracturing at least a portion of the at least one seal; and

- means for controllably releasing a liquid, positionable within the cavity, out of the cavity.

2. The fluid reservoir of claim 1, wherein the at least one seal comprises a first seal and a second seal, further defining the cavity therebetween.

3. The fluid reservoir of claim 2, wherein the fracturing means is associated with the first seal.

4. The fluid reservoir according to claim 1, wherein one of the top and bottom surfaces includes means for directing released fluid to a region adjacent the fluid reservoir.

5. The fluid reservoir of claim 4, wherein the flow direction means comprises at least one slit in the associated top or bottom surface.

6. The fluid reservoir of claim 1, wherein at least a portion of the top surface is deformable upon exertion of a force.

7. The fluid reservoir of claim 1, wherein the at least one seal comprises at least a first region of attachment and a second region of attachment;

- the fracturing means comprises the first region of attachment having a weaker attachment than the second region of attachment.

8. The fluid reservoir of claim 1, wherein the control means comprises at least a portion of the seal having a pinch-like configuration.

9. The fluid reservoir of claim 1, wherein the fluid reservoir can be configured in numerous geometrical patterns, one of which is selected from the group consisting of circles, ovals, rectangles, and squares.

10. The fluid reservoir of claim 2, wherein the fluid reservoir is oval in shape, and the first and second seals are concentric with one another.

11. An electrode assembly for use with a drug delivery device, comprising:

- means for carrying a medicament;
- an active electrode in electrical communication with the carrying means;
- at least two passive electrodes; and

- means for securing the electrode assembly to a surface of a patient, wherein upon securement the active electrode is distally spaced from the at least two passive electrodes, and the at least two passive electrodes are distally spaced from each other.

12. The electrode assembly of claim 11, wherein the at least two passive electrodes are spaced on opposite sides of the active electrode, relative to one another.

13. The electrode assembly of claim 11, wherein the medicament carrying means comprises a
5 dispersive pad.

14. The electrode assembly of claim 11, wherein the carrying means comprises a gel sponge.

15. The electrode assembly of claim 11, further including a medicament migration barrier region adjacent the medicament carrying means.

16. The electrode assembly of claim 15, wherein the medicament migration barrier is spaced from the dispersive pad, creating a moat region therebetween.

17. The invention of claim 11, wherein the electrode assembly further comprises a separator pad having a surface, and the securing means comprises at least a portion of the surface of the
15 separator pad having an adhesive.

18. The electrode assembly of claim 17, wherein the separator pad additionally comprises means
20 for preventing migration of a medicament.

19. The electrode assembly of claim 18, wherein the separator pad is positioned adjacent the active electrode and at least one of the at least two passive electrodes.

20. The electrode assembly of claim 11, wherein the securing means comprises an electrically conductive adhesive attached to the at least two passive electrodes.

21. The electrode assembly of claim 20, wherein the electrically conductive adhesive comprises
5 Gum Karaya.

22. The invention of claim 11, wherein the electrode assembly further comprises at least one fluid reservoir capable of retaining a medicament, and an assembly tray, the assembly tray being configured to hold the electrode assembly and the at least one fluid reservoir;

- the assembly tray comprising a substantially rigid surface, the rigid surface being capable of deformation upon application of a force.

23. The invention of claim 22, wherein the electrode assembly further comprises a separation barrier adjacent the medicament carrying means and the at least two passive electrodes, the
15 separation barrier comprising means for preventing migration of a medicament.

24. The invention according to claim 23, wherein the separation barrier is spaced from the medicament carrying means, creating a moat region therebetween.

20 25. The invention of claim 22, wherein the at least one fluid reservoir comprises at least two fluid reservoirs.

26. An electrode assembly for use with a drug delivery device, comprising:

- means for carrying a medicament;
- means for preventing the migration of a medicament spaced from the carrying means,

creating a moat region therebetween;

- 5 - an active electrode in electrical communication with the carrying means;
- at least one passive electrode; and
- means for securing the electrode assembly to a surface of a patient.

27. The electrode assembly of claim 26, wherein the at least one passive electrode comprises at least two passive electrodes.

28. The electrode assembly of claim 27, wherein the securing means secures the electrode to a surface of a patient with the active electrode distally spaced from the at least two passive electrodes, and the at least two passive electrodes are distally spaced from one another.

29. The electrode assembly of claim 27, wherein the at least two passive electrodes are spaced on opposite sides of the active electrode, relative to one another.

30. The electrode assembly of claim 26, wherein the medicament carrying means comprises a
20 dispersive pad.

31. The electrode assembly of claim 26, wherein the medicament carrying means comprises a gel sponge.

32. The invention of claim 26, wherein the electrode assembly further comprises a separator pad having a surface, the securing means comprises at least a portion of the surface of the separator pad having an adhesive.

33. The electrode assembly of claim 26, wherein the securing means comprises an electrically conductive adhesive attached to the at least one passive electrode.

34. The electrode assembly of claim 33, wherein the electrically conductive adhesive comprises Gum Karaya.

35. The invention of claim 26, wherein the electrode assembly further comprises at least one fluid reservoir capable of retaining a medicament, and an assembly tray, the assembly tray being configured to hold the electrode assembly and the fluid reservoir;

- the assembly tray comprising a substantially rigid surface, the rigid surface being capable of deformation upon application of a force.

36. The invention of claim 35, wherein the at least one fluid reservoir comprises at least two fluid reservoirs.

37. An electrode assembly for use with a drug delivery device, comprising:

- means for carrying a medicament;

- an active electrode, in electrical communication with the carrying means, comprising a silver conductive element;

- at least one passive electrode, comprising a carbon conductive element; and
- means for securing the electrode assembly to a surface of a patient.

38. The electrode assembly of claim 37, wherein the at least one passive electrode comprises at
5 least two passive electrodes.

39. The electrode assembly of claim 38, wherein the at least two passive electrodes are spaced
on opposite sides of the active electrode, relative to one another.

40. The electrode assembly of claim 37, wherein the medicament carrying means comprises a
dispersive pad.

41. The electrode assembly of claim 37, wherein the medicament carrying means comprises a
gel sponge.

42. The electrode assembly of claim 37, further including a medicament migration barrier region
adjacent the medicament carrying means.

43. The electrode assembly of claim 42, wherein the medicament migration barrier is spaced
20 from the dispersive pad, creating a moat region therebetween.

44. The invention of claim 37, wherein the electrode assembly further comprises a separator pad having a surface, the securing means comprises at least a portion of the surface of the separator pad having an adhesive.

5 45. The electrode assembly of claim 44, wherein the separator pad additionally comprises means for preventing migration of a medicament.

46. The electrode assembly of claim 44, wherein the separator pad is positioned adjacent the active electrode and at least one of the at least two passive electrodes.

47. The electrode assembly of claim 37, wherein the securing means comprises an electrically conductive adhesive attached to the at least two passive electrodes.

48. The electrode assembly of claim 47, wherein the electrically conductive adhesive comprises Gum Karaya.

49. The invention of claim 37, wherein the electrode assembly further comprises a fluid reservoir capable of retaining a medicament, and an assembly tray, the assembly tray being configured to hold the electrode assembly and the fluid reservoir;

20 - the assembly tray comprising a substantially rigid surface, the rigid surface being capable of deformation upon application of a force.

50. The invention of claim 49, wherein the electrode assembly further comprises a separation barrier adjacent the medicament carrying means and the at least two passive electrodes, the separation barrier comprising means for preventing migration of a medicament.

51. An iontophoretic drug delivery apparatus, comprising:

- a fluid reservoir capable of retaining a medicament, the fluid reservoir comprising:
 - a sealed fluid chamber having a top surface and a bottom surface, and a cavity therebetween, the cavity being at least partially defined by at least one seal, wherein the cavity serves to house a fluid therewithin;
 - means associated with the sealed fluid chamber for enabling release of a fluid therefrom; and
 - means for controllably releasing a liquid, positionable within the cavity, out of the cavity;
- an electrode assembly associated with the fluid reservoir, comprising:
 - means for carrying a medicament;
 - an active electrode in electrical communication with the carrying means;
 - at least two passive electrodes;
 - means for preventing the migration of a medicament, adjacent the active electrode and the at least two passive electrodes, spaced from the active electrode, creating a moat region therebetween; and
 - means for securing the electrode assembly to a surface of a patient, wherein upon securement the active electrode is distally spaced from the at least two passive electrodes, and the at least two passive electrodes are distally spaced from

each other; and

- a tray assembly configured to hold both the fluid reservoir and the electrode assembly in their relative positions, the tray assembly comprising:

- a substantially rigid surface, capable of deformation upon application of a force;

and

- means for storing the completed assembly.

52. The apparatus of claim 51, wherein the active electrode comprises a silver conductive element.

53. The apparatus of claim 51, wherein at least one of the at least two passive electrodes comprises a carbon conductive element.

54. The apparatus of claim 53, wherein all of the at least two passive electrodes comprise carbon conductive elements.

55. A method for releasing a fluid from a fluid reservoir, the method comprising the steps of:

- depressing at least a portion of a sealed fluid chamber, wherein the fluid chamber

includes a cavity at least partially defined by at least one seal, having a fluid therewithin;

- fracturing at least a portion of the at least one seal; and

- controllably releasing the fluid out of the cavity.

56. The method of claim 55, wherein the fluid chamber additionally comprises a top surface and a bottom surface, the step of depressing comprising deforming at least a portion of the top surface.

5 57. The method of claim 55, wherein the at least one seal comprises a first seal and a second seal, the step of fracturing at least one seal comprises the step of fracturing the first seal.

58. The method of claim 55, wherein the at least one seal comprises a first region of attachment and a second region of attachment, the step of fracturing comprising fracturing at least a portion of the first region of attachment.

59. The method of claim 55, wherein the at least one seal comprises at least a portion having a pinch-like configuration, the step of controllably releasing comprising fracturing at least a portion of the at least one seal at the pinch-like configuration.

60. A method for iontophoretically administering a medicament to a patient using an electrode assembly, the method comprising the steps of:

- impregnating a means for carrying a medicament, associated with an electrode assembly, with a medicament;

20 - applying the electrode assembly to a surface of a patient, wherein the electrode assembly comprises an active electrode and at least two passive electrodes, the step of applying comprising

- placing the active electrode in distally spaced relation to the at least two passive electrodes, and

- placing the at least two passive electrodes in distally spaced relation to one another;

5 - applying an electrical potential across the active electrode, the surface of the skin, and the at least two passive electrodes in such a way so as to drive the impregnated medicament from the carrying means and into the skin.

61. The method according to claim 60, wherein the step of placing the at least two passive electrodes comprises placing the at least two passive electrodes on opposite sides of the active electrode.

62. The method according to claim 60, wherein the step of applying the electrode assembly additionally comprises the step of applying a migration prevention means to the surface in distal
15 relation to the active electrode.

63. A method for iontophoretically administering a medicament to a patient using an electrode assembly, the method comprising the steps of:

20 - impregnating a means for carrying a medicament, associated with an electrode assembly, with a medicament;

 - applying the electrode assembly to a surface of a skin, wherein the electrode assembly comprises an active electrode, at least one passive electrode and means for preventing the migration of a medicament, the step of applying comprising:

- placing the active electrode in distally spaced relation to the at least one passive electrodes, and

- placing the migration prevention means in distal relation to the active electrode, creating a moat region therebetween;

5 - applying an electrical potential across the active electrode, the surface of the skin, and the at least two passive electrodes in such a way so as to drive the impregnated medicament from the carrying means and into the skin.

64. The method according to claim 63, wherein the at least one passive electrode comprises at least two passive electrodes, and the step of placing the electrodes comprises:

- placing the active electrode in distally spaced relation to that at least two passive electrodes; and

- placing the at least two passive electrodes in distally spaced relation to one another.

15 65. A method for iontophoretically applying a medicament to a patient, comprising:

- applying a force to a top surface of a fluid reservoir, associated with an electrode assembly, the fluid reservoir having a cavity and a fluid contained therein;

- compressing at least a portion of the top surface of the fluid reservoir;

- fracturing at least a portion of a first region of at least one seal of the fluid reservoir,

20 while substantially maintaining the integrity of a second region of the at least one seal;

- releasing the fluid from the cavity within the fluid reservoir;

- directing the flow of the released fluid, out of the cavity, and onto a medicament carrying means, a part of the electrode assembly; and

- iontophoretically administering the medicament to a patient using the electrode assembly.

66. A method for iontophoretically applying a stored medicament to a patient, comprising:

5 - removing a tray assembly from storage, the tray assembly comprising a substantially rigid shell, configured to hold a fluid reservoir and an electrode assembly in relative positions, and a removable cover;

 - applying force to a portion of the shell, associated with the fluid reservoir;
 - compressing at least a portion of the shell into a top surface of the fluid reservoir;
 - fracturing at least a portion of a first region of at least one seal of the fluid reservoir, while substantially maintaining the integrity of a second region of the at least one seal;
 - releasing a fluid from a cavity within the fluid reservoir;
 - directing the flow of a released fluid out of the cavity, and onto a medicament carrying means, a part of the electrode assembly;

15 - removing the electrode assembly from the tray assembly;
 - applying the electrode assembly to a surface of a patient, wherein the step of applying further comprises:

 - placing an active electrode, in electrical communication with the medicament carrying means, in distally spaced relation to at least two passive electrodes;

20 - placing the at least two passive electrodes in distally spaced relation to one another; and

 - iontophoretically administering the fluid to a patient using the electrode assembly.